



November 5, 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS -810)
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

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DEC - 1 2003

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), at 825 Challenger Drive, Green Bay, Wisconsin, 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. PhytoPharmica wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	Probiotic Pearls™ is a probiotic dietary supplement designed to help support digestion and a healthy intestinal system.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: *Robert Doster*

Title: Senior Vice President of Scientific Affairs

Date: 11/5/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

Probiotic Pearls 23p

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13389

825 CHALLENGER DRIVE
GREEN BAY, WI 54311-8328
920-469-9099
TOLL FREE 800-553-2370
FAX 920-469-4418
FAX TOLL FREE 888-311-5657
WWW.PHYTOPHARMICA.COM



November 5, 2003

Office of Nutritional Products, Labeling and
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 5100 Paint Branch Parkway
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	Lactobacillus acidophilus and Bifidobacterium longum have been shown to possess immunoprotective/immuno-modulatory properties.* These benefits include modulation of : cytokine and various interleukin production, autoimmunity, natural killer cell cytotoxicity, lymphocyte proliferation, and antibody production.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: _____

Robert Doster

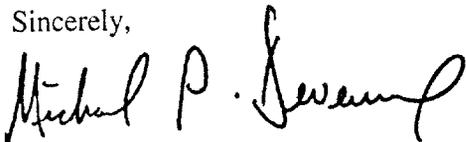
Title: Senior Vice President of Scientific Affairs

Date: 11/5/03

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer



November 6, 2003

Office of Nutritional Products, Labeling and
Dietary Supplements (HFS -810)
Center for Food Safety and Applied Nutrition,
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5100 Paint Branch Parkway
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	In an open, randomized, controlled trial, Lactobacillus acidophilus and Bifidobacterium bifidum were supportive of colon health in older adults.* In addition, B cell (important antibody producing immune cells) levels increased as compared with the untreated group.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: Robert Doster
Robert Doster

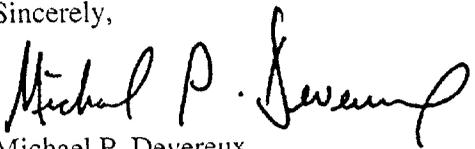
Title: Senior Vice President of Scientific Affairs

Date: 11/6/03

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Sincerely,



Michael P. Devereux
Chief Financial Officer



November 6, 2003

Office of Nutritional Products, Labeling and
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Center for Food Safety and Applied Nutrition,
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5100 Paint Branch Parkway
College Park, MD 20740

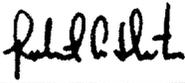
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	Oral ingestion of probiotics produces a stabilizing effect on the gut flora.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: 

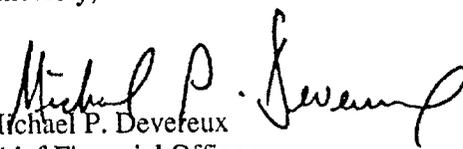
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/6/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer

Probiotic Pearls 27p

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PhytoPharmica
NATURAL MEDICINES™

November 7, 2003

Office of Nutritional Products, Labeling and
Dietary Supplements (HFS -810)
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

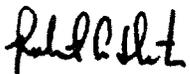
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	Lactobacillus acidophilus and Bifidobacterium longum also help support the better utilization and bioavailability of nutrients, including vitamins, minerals, proteins, fats, and carbohydrates.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

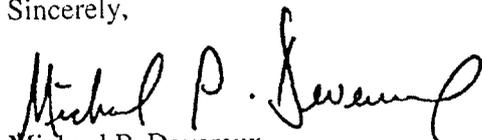
Title: Senior Vice President of Scientific Affairs

Date: 11/7/03

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Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized "M" and "D".

Michael P. Devereux
Chief Financial Officer



November 8, 2003

Office of Nutritional Products, Labeling and
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5100 Paint Branch Parkway
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	Probiotics have been shown to help retain healthy levels of C. albicans that are already within normal limits.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/8/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer



November 9, 2003

Office of Nutritional Products, Labeling and
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	The patented seamless pearl capsule of Probiotic Pearls™ assures that virtually all the bacteria remain uninjured and healthy to colonize in the intestine.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica, (a Division of Integrative Therapeutics, Inc.), has substantiation that the statements are truthful and not misleading.

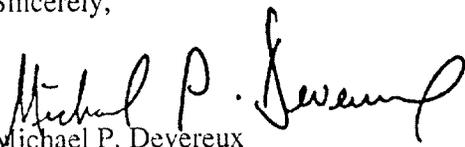
By: Robert Doster
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/9/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,


Michael P. Devereux
Chief Financial Officer